

**DRUG AND DEVICE ACTIONABLE BECAUSE OF POTENTIAL DANGER
WHEN USED ACCORDING TO DIRECTIONS**

3581. Misbranding of Special Formula capsules. U. S. v. 1 Drum * * *.
(F. D. C. No. 31191. Sample No. 21432-L.)

LIBEL FILED: June 12, 1951, Northern District of Alabama.

ALLEGED SHIPMENT: On or about April 30, 1951, by the Rowell Laboratories, from Baudette, Minn.

PRODUCT: 1 5,000-capsule drum of *Special Formula capsules* at Ashland, Ala., in possession of the J. Q. Adams Drug Co.

Analysis showed that the product contained approximately 8 grains of arsenic trioxide per capsule.

RESULTS OF INVESTIGATION: The J. Q. Adams Drug Co. repackaged and relabeled a portion of the contents of the drum into boxes. At the time of seizure there were approximately 4,250 capsules in the drum, 53 boxes of the repackaged product, and a supply of empty boxes in the possession of the above company.

LABEL, IN PART: (Drum) "5000 Capsules Special Formula Each Capsule contains Ingredients Arsenous Acid * * * (Arsenic Trioxide) 10 grains Caution: To be used only on or by the prescription of a physician or veterinarian. * * *"; (repackaged product, box) "Wonder Mange Capsules (canine) * * * Each capsule contains 10 grains Sodium 2 Arsenious Acid * * *."

NATURE OF CHARGE: Misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration recommended in its labeling, namely (box label), "One capsule every 3 days until symptoms disappear"; and, Section 502 (a), the statement on the box label "Mange Capsules (canine) These capsules may be used in the treatment of all types of Mange on dogs" was false and misleading since the article was not effective in the treatment of mange on dogs, and the statement also on the box label "Sodium 2 Arsenious Acid" was false and misleading since the article contained no sodium compound. The article was misbranded in the above respects while held for sale after shipment in interstate commerce.

Further misbranding, Section 502 (f) (1), the labeling of the capsules in the drum failed to bear adequate directions for use. The article was misbranded in the above respect when introduced into and while in interstate commerce.

DISPOSITION: July 24, 1951. Default decree of condemnation and destruction.

3582. Misbranding of Hydr-Oxy-Colon device. U. S. v. 1 Device, etc. (F. D. C. No. 31736. Sample No. 21292-L.)

LIBEL FILED: October 3, 1951, Southern District of Mississippi.

ALLEGED SHIPMENT: On or about July 16 and 21, 1951, by the United X-Ray & Equipment Co., from Los Angeles, Calif., and Dallas, Tex.

PRODUCT: 1 *Hydr-Oxy-Colon device* at Natchez, Miss., together with a 12-page booklet entitled "Dewelles Detoxacolon Oxygen Therapy," a 2-page treatment chart headed "Pathology Location Appearance Treatment," copy for use in preparing newspaper advertising entitled "Something New Has Been Added," and copy for preparing postal cards entitled "Free To You."

The device was designed for the administration of mixed oxygen and water as an enema.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the accompanying printed matter described above were false and misleading. The statements and designs represented and suggested that the device was an adequate and effective treatment for asthma, diabetes, arthritis, high blood pressure, low blood pressure, kidney disorders, neuritis, colitis, prolapse of the rectum and sigmoid, spastic colitis, ulcerative colitis, ptosis of the colon, spasticity of the rectum, extreme ulceration of the lower bowel, common cold, sinusitis, dysentery, flaccid condition of the sphincters, amebic dysentery, heart conditions, hay fever, acute coryza, anemia, epilepsy, toxemias of pregnancy, and infections and inflammations of the female reproductive organs; that the device was an excellent treatment following childbirth to return muscle tone; that it would eliminate distress and disease; and that it would correct chronic ailments or pathological changes and bring about a restoration of health. The device was not an adequate and effective treatment for such disease conditions, and it was not capable of fulfilling the promises of benefit made for it.

Further misbranding, Section 502 (j), the article was dangerous to health when used with the frequency and duration prescribed, recommended, and suggested in its labeling since in the post partum period and in the acute stages of vaginal infections, treatment as directed would force infective material into or through the cervical canal, resulting in ascending infection with probable serious consequences to the health of the patient.

The device was misbranded in the above respects when introduced into, while in, and while held for sale after shipment in, interstate commerce.

DISPOSITION: November 20, 1951. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

3583. Misbranding of C. M. A. Formula B.-88, C. M. A. Formula K & B 55, Hancock's Formula No. 4, C. M. A. Formula S.-99, C. M. A. Formula S.L.-22, C. M. A. Old Style Indian Herb Medicine #10, and sugar tablets, and refusal to permit inspection. U. S. v. Coordinative Medicines Assn., Inc. (C. M. A., Hancock Medicine Co., and Christian Mutual Assn.), and Robert E. Davis and Carrie Davis. Pleas of not guilty. Tried to the court. Verdict of guilty. Corporation fined \$800, Robert E. Davis, \$1,000, and Carrie Davis, \$400. Robert E. Davis and Carrie Davis each sentenced to 2 years in prison; prison sentences suspended and each individual defendant placed on probation for 3 years. (F. D. C. No. 30027. Sample Nos. 51990-K, 51992-K, 54535-K, 54536-K, 54542-K to 54545-K, incl.)

INFORMATION FILED: February 9, 1951, Southern District of Indiana, against Coordinative Medicines Assn., Inc., Indianapolis, Ind., also trading under the names of C. M. A., Hancock Medicine Co., and Christian Mutual Assn., and against Robert E. Davis, president, and Carrie Davis, secretary-treasurer of the corporation.

ALLEGED VIOLATION: Between November 1949 and on or about March 2, 1950, the defendants caused to be introduced into interstate commerce at Indianapolis, Ind., for delivery into the States of Ohio, Mississippi, and Alabama,

*See also No. 3581 (human and veterinary use).